

### Remarks

Claims 34-45 are pending in the application. All claims were previously rejected under 35 U.S.C. § 112, under 35 U.S.C. § 103, and for obviousness-type double patenting. The rejections under 35 U.S.C. § 112 have now been removed. The prior rejections under 35 U.S.C. § 103 have apparently also been removed. The double-patenting rejection remains, but is a provisional rejection and Applicant has previously indicated that no further comment will be provided until such time as an actual rejection is levied. The Final Office Action also contains two “new” rejections under 35 U.S.C. § 103. The “new” § 103 rejections differ from prior § 103 rejections only in that additional secondary references have been added to the combination.

Applicant has previously explained the many reasons that the base reference (WO 99/38978; “the ‘978 publication”) cannot teach or suggest the claimed invention, whether alone or in combination with various cited references. None of these arguments is addressed, or even acknowledged, in the Final Office Action. As discussed below, Applicant submits that the Final Office Action is defective and should be withdrawn for this reason alone.

Moreover, Applicant points out that the “new” combinations cited by the Examiner do nothing to solve the previously-addressed deficiencies of the ‘978 publication, alone or in combination with the various secondary references. Indeed, the “new” combinations in fact represent a re-sorting of old combinations, with the further addition of yet more secondary references that are not even asserted to disclose core features of the present claims.

To be absolutely direct, the ‘978 publication, whether alone or in combination with any of the cited references, does not teach or suggest a modified peanut allergen “encapsulated inside” dead *E. coli*, as recited in the present claims. Furthermore, the ‘978 publication does not teach or suggest any *pharmaceutical composition* comprising encapsulated peanut allergens, as recited in the present claims. Indeed, as has been extensively discussed, several of the secondary references *teach explicitly away* from the claimed invention. To give but one example, some secondary references *require live* bacteria. There is absolutely no combination of these cited references that could teach or suggest the claimed invention.

The *sole* statement made by the Examiner with regard to “encapsulated inside” is that urea is used to solubilize a protein produced in the ‘978 publication. This statement is wholly irrelevant to the present claims.

First, the protein being solubilized with urea in the '978 publication is *not* a modified peanut allergen as recited in the present claims. That is, the '978 publication is describing urea purification of a *different protein*.

Second, the fact that the '978 inventors used urea in purifying a protein does not mean that the protein is "encapsulated within" bacteria.

Third, clearly, if the '978 inventors are isolating protein *from* dead *E. coli*, they are not preparing the dead *E. coli* as a *pharmaceutical composition*, as recited in the present claims.

For all of these reasons, the '978 publication cannot teach or suggest *pharmaceutical compositions of modified* peanut allergens *encapsulated inside* dead *E. coli*. The Examiner cannot continue to ignore these points.

No list of secondary references, however long, is meaningful unless the cited secondary references in fact address the deficiencies of the primary reference. Moreover, the Examiner must take the teachings of the secondary references *as a whole* and may not ignore those portions that inconveniently teach away from the Examiner's intended combination, or from the claimed invention.

The "new" rejections levied in the Final Office Action add nothing substantive to the previously-levied rejections, yet the Final Office Action has not a single remark addressing, or even acknowledging, Applicant's prior arguments or amendments. The Manual of Patent Examining Procedures ("MPEP") requires more. Indeed, the MPEP states, "Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, *take note of the applicant's argument and answer the substance of it.*" MPEP § 701.07(f) (emphasis added). Further, in the form paragraphs provided for Examiners use in establishing that "Arguments Are Not Persuasive" in an Office Action, the MPEP states, "*The examiner must address all arguments which have not already been responded to in the statement of the rejection.*" MPEP § 7.37 (emphasis added). In the present case, the Examiner did not respond to a *single one* of Applicant's previous arguments, or even acknowledge that they *existed*.

For all of these reasons, Applicant submits that the rejections levied in the Final Office Action are improper and should be removed. The present claims are not obvious over the cited art and are allowable. A Notice to that effect is respectfully requested.

If, at any time, it appears that a phone discussion would be helpful, the undersigned would greatly appreciate the opportunity to discuss such issues at the Examiner's convenience. The undersigned can be contacted at (617) 248-5175.

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Respectfully submitted,

/BHJarrell/  
Brenda Herschbach Jarrell, Ph.D.  
Registration Number: 39,223

Choate, Hall & Stewart LLP  
Two International Place  
Boston, MA 02110  
t (617) 248-5175  
f (617) 248-4000  
bjarrell@choate.com  
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